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Country Report

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Report Highlights:
This report gives an overview of EU food laws currently in force. Updated sections include: labeling requirements, additives, pesticides, GM foods, novel foods, beef labeling, wine, organic foods, and import duties.

Includes PSD changes: No
Includes Trade Matrix: No
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DISCLAIMER: This report was prepared by the Office of Agricultural Affairs, U.S. Mission to the European Union, for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

SECTION 1. FOOD LAWS

The European Union (EU), formerly known as the European Economic Community (EEC), was created by the Treaty of Rome on March 25, 1957, and after several accessions comprises currently 15 Member countries : France, Germany, Italy, Netherlands, Belgium, Luxembourg, Ireland, Denmark, the United Kingdom, Spain, Portugal, Greece, Austria, Sweden and Finland. Making up the world's largest multi-nation trading bloc, EU Member countries accept the entire body of EU laws and obligations associated with the treaties and agreements to which the EU is a party.

Ten central and eastern European countries (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia) are expected to join the EU in 2004. Once they are a member of the EU, they will also be obliged to apply EU laws and rules pertaining to all sectors and commodities, including processed foods.

Originally created as a customs union, the EU slowly is becoming a single market. Harmonizing legislation between the 15 Member States, however, is a lengthy process, and by no means is the single market a *fait accompli*. It is important to note that when EU-wide legislation is incomplete or absent, the laws of Member States apply, often resulting in different rules in different Member States.

EU political structures include the permanent bureaucracy of the Commission, the Council of Member State representatives, and the European Parliament. All are involved in creating and passing legislation. For more information on how the EU works, see the website of the European Commission at http://europa.eu.int/index-en.htm.

Over time, a vast amount of rules pertaining to food have been developed. However, it took for the politically challenging environment in the aftermath of the BSE crisies and several other food safety scandals to establish a general EU food law. The basic framework Regulation EC No 178/2002, published in January 2002 sets out the general principles and requirements of EU food law and particularly the concept of traceability, for all food and feed products. At the same time, this regulation created the European Food Safety Authority (EFSA), which will have major responsibility in providing scientific advise for the legislators .

EU legislation is made up of Directives and Regulations –all translated into the 11 official EU languages– which must be implemented at the Member State level. **Directives** define the result that must be achieved but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption). **Regulations** are binding in their entirety and automatically enter into force on a set date in all Member States. Directives are more common than regulations. Amendments to EU legislation are usually published in new and separate Directives and Regulations, making it difficult to be sure of all possible amendments when doing research. When legislation is referenced in this guide, it is implied that all further amendments also apply.

To date, framework rules exist in most subject areas. However, many specific directives/regulations

still need to be drawn up and adopted: e.g. specific directives on food contact materials and on foods for particular nutritional uses.

The EU has followed a dual approach in harmonizing food laws: "horizontal" legislation that covers aspects which are common to all foodstuffs (such as additives, labeling and hygiene, etc.) and "vertical" legislation on specific products (e.g., cocoa and chocolate products, sugars, honey, fruit juices, fruit jams, novel foods, etc.). Still under discussion are legislative initiatives for issues such as standards for fortified foods (allowed in some Member States and prohibited in others), nutrition and functional claims, and allergen labeling.

Imported products must meet existing Member State requirements in cases where EU regulatory harmonization is not yet complete.

The main principle of the single market concept is to ensure that all food products, whether produced in the EU or imported from a third country, can move freely throughout the EU if they comply with the directives. In reality, certain directives allow Member States to make exceptions e.g. in cases where a country can prove health concerns about a product intended for import. Free movement can only be guaranteed when all aspects are covered by harmonized legislation: e.g. a foodstuff may comply with the labeling directive but be pre-packed in a material for which harmonized rules do not yet exist.

Enforcement of EU food legislation is done by Member State officials. Auditing oversight of Member State performance is done by EU Commission officials in Brussels. The EU Commission has the power to initiate legal action in the European Court of Justice against Member States who are not complying with EU Directives and Regulations.

Exporters should be aware that there may also be some variation among Member States in applying EU harmonized legislation: this may be due to variations in the transitional period needed to adjust to EU rules; there may be temporary waivers or exemptions –usually called derogations; in certain cases there may be room for interpretation of EU harmonized legislation; certain aspects which are not regulated in detail at EU level may be handled differently in different Member States, e.g. acceptability of stick-on labels varies among Member States. Also, there is a wide variation in inspection fees, in registration fees and in the time required to evaluate dossiers on products used in the course of the food production process.

Up to date information on EU food import rules as well as general information on EU import duties and quotas can be found on our website at http://www.useu.be/agri/usda.html. The website also links to additional sources of useful information.

FAIRS reports prepared by the Offices of Agricultural Affairs in each Member State are excellent sources of information on member state specific rules and can be found at www.useu.be/agri/fairs.html.

AS A REMINDER! Imports of red meat, meat products, farm and wild game meat, ratites, milk and milk products, seafood, bovine embryos and semen, porcine and equine semen, gelatin and animal casings to the EU from the United States may only originate

SECTION 2. LABELING REQUIREMENTS

www.useu.be/agri/label.html

A. General Requirements

The standard U.S. label fails to comply with EU labeling requirements.

The main rules on the labeling, presentation and advertising of foodstuffs marketed in the EU are laid down in European Parliament and Council Directive 2000/13/EC + corrigendum (English version of Annex 3). It applies not only to foodstuffs intended for sale to the ultimate consumer but also for supply to restaurants, hospitals and other mass caterers. Specific labeling provisions for genetically modified foods and for novel foods have been established in Council Regulation 1139/98, Commission Regulation 50/2000, European Parliament and Council Regulation 258/97.

Compulsory Information

– the name under which the product is sold

– the list of ingredients, in descending order of weight. Important exceptions include added water in foods reconstituted from concentrates, and cheese, which is covered by special rules. The following ingredients require a specific statement on the label: GMO's, packaging gases, sweeteners, aspartame and polyols, quinine and caffeine. As concerns about allergens rise, it should be noted that sub-ingredients of an ingredient constituting less than 25 percent of the finished product do not need to be listed separately, e.g. if ten percent of a packaged salad is mayonnaise, the label need not break out the oil or eggs that make up the mayonnaise.

– certain ingredients may be designated by the name of the category rather than the specific name. These include fats, oils, starch, fish, cheese, spices, herbs, gum bases, crumbs, sugar, dextrose, glucose syrup, milk proteins, cocoa butter, crystallized fruit, vegetables and wine. Directive 2001/101/EC adds meat as a category and defines the term "meat" for the labeling of pre-packed meat-based products.

– the quantity of certain ingredients or categories of ingredients (QUID) - See below

– the net quantity of prepackaged foodstuffs expressed in metric units (liter, centiliter, milliliter, kilogram or gram).

– the shelf life is indicated by the words "Best before..." when the date includes an indication of the day, or by "Best before end of..." in other cases. The date has to be given in order of day- month-year. However, for foodstuffs with a shelf life of less than three months, the day and month of expiry are adequate; for a shelf life of three to eighteen months the month and year are sufficient; for more than eighteen months shelf life the year is sufficient indication. In the case of highly perishable foodstuffs the

date consisting of the day, the month and possibly the year has to be preceded by the words "use by."

– any special storage conditions or conditions of use

– the name or business name and address of the manufacturer, packager or vendor established within the Community

– particulars of the place of origin or provenance in case absence of such information might mislead the consumer

– instructions for use

– the actual alcoholic strength for beverages containing more than 1.2 percent alcohol by volume

– a mark to identify the lot to which a foodstuff belongs, determined by the producer, manufacturer or packager or by the first seller in the EU. The marking shall be preceded by the letter "L" except in cases when it is clearly distinguishable from other indications on the label. The lot identification is not necessary if the date (day and month) of minimum durability or "use by" date, appears in un-coded form on the label.

– treatments undergone, with specific indications for irradiated foods and deep-frozen foods (see section 7)

Additives

– Annex II to the labeling directive lists the categories of additives which must be designated by the name of their category followed by their specific name or EEC number. The categories are the following: color, preservative, anti-oxidant, emulsifier, thickener, gelling agent, stabilizer, flavor enhancer, acid, acidity regulator, anti-caking agent, modified starch, sweetener, raising agent, anti-foaming agent, glazing agent, emulsifying salts, flour treatment agent, firming agent, humectant, bulking agent, propellent gas.

– flavorings: Annex III to the labeling directive describes the way of designating flavorings in the list of ingredients.

– the presence of sweeteners/aspartame/polyols requires standardized statements on the label; packaging gases are not considered as additive but also require a standardized statement

Quinine and Caffeine

Commission Directive 2002/67/EC, scheduled to come into force by July 2004, requires the compulsory labeling of quinine and caffeine used in the production or preparation of foodstuffs (usually tonic waters and energy drinks). Quinine and caffeine must be mentioned in the ingredients list, preceded by the term "flavoring". Beverages containing more than 150 mg of caffeine per liter will have

to be labeled with "high caffeine content" followed by the caffeine content expressed in mg/100 ml.

Quantitative Ingredients Declaration (QUID)

Quantitative ingredients declaration (QUID) is compulsory in the following cases:

– where the ingredient or category of ingredients appears in the name under which the foodstuff is sold:
e.g. "15% strawberries" on strawberry ice cream - QUID for strawberries
"35% fruit" on fruit pie - QUID for total fruit content

– where the ingredient or category of ingredients is usually associated with that name by the consumer:
e.g. goulash soup - QUID for beef

– where the ingredient or category of ingredients is emphasized on the labeling in words (e.g. "made with butter"), pictures (e.g. of a cow to emphasize dairy ingredients) or graphics (different size, color and/or style of print)

– where the ingredient or category of ingredients is essential to characterize a foodstuff and to distinguish it from similar products

The QUID declaration must be indicated in or immediately next to the name under which the product is sold, unless a list of ingredients is voluntarily indicated on the label in which case the quantity may appear in the list. The quantity of the ingredient, expressed as a percentage, must correspond to the quantity of the ingredient(s) actually used in the preparation of the product.

The QUID requirement DOES NOT apply to constituents naturally present in foods and which have not been added as ingredients e.g. caffeine (in coffee) and vitamins and minerals (in fruit juices). QUID declarations are not needed in a number of cases, e.g. when products state the drained net weight or where an ingredient is used for purposes of flavoring. QUID declarations CANNOT replace nutrition labeling.

Commission Directive 1999/10/EC provides for exemptions from the QUID requirement:

- when the wording "with sweeteners" or "with sugar(s) and sweetener(s) accompanies the name under which a foodstuff is sold
- when the addition of vitamins and minerals is subject to nutrition labeling
- when foodstuffs are concentrated or dehydrated

General guidelines have been drawn up to help Member States and industry organizations implement the principle of QUID. A copy of these guidelines can be obtained from our office upon request or from our website.

Language Requirements

As a general rule, labeling has to be in a language easily understood by consumers; this is in practice the official language(s) of the member state. As an exception to the general rule, it is also allowed to use:

- another language, provided it can easily be understood by consumers
- other means depicting the content (e.g. pictures)

Multi-language labeling is allowed throughout the EU. Exporters are advised to consult the member state FAIRS reports for the exact language requirements in their market (www.useu.be/agri/fairs.html).

Stick-on Labels

EU legislation does not contain any reference to the use of stick-on labels. It is up to individual Member States whether to accept stick-on labels.

Samples

EU legislation covers all foods destined for consumption. It does not contain any specific labeling requirements or exceptions for samples.

Labeling of Genetically Modified Foods and of Novel Foods

Section 7 of this report is entirely dedicated to the regulatory review and commercialization of genetically modified foods in the EU and provides information on the circumstances in which genetically modified foods and their derivatives have to be labeled. The words "produced from genetically modified ..." or "genetically modified" as a footnote or specification following the ingredient have to be used to indicate the presence of the GM soy and corn proteins and all GM additives and flavorings that are currently on the market.

B. Medical / Health Claims

Medical claims, attributing to a foodstuff the property of preventing, treating or curing human diseases, are explicitly prohibited in the EU general labeling directive. However, this directive does not provide any guidance on which health claims (e.g."Aids Digestion") are allowed and which are not. As a result, many EU Member States have developed separate initiatives in this area.

Requirements Specific to Nutritional Labeling

Nutrition labeling is not mandatory in the EU unless a nutrition claim is made on the label or in advertising messages. "Nutrition labeling" means any information on the label that relates to energy value and to the following nutrients: protein, carbohydrate, fat, fibre, sodium, vitamins and minerals present in significant amounts. A "nutrition claim" means any representation or advertising that claims that a foodstuff has particular nutritional properties and is only allowed if it relates to the energy value and/or nutrients referred to above. Nutrition labeling rules are laid down in Council Directive 90/496/EEC.

Where nutritional labeling is provided, the information to be given should consist of either group 1 or

group 2 in the following order:

Group 1: - the energy value
- the amount of protein, carbohydrate and fat

Group 2: - the energy value
- the amount of protein, carbohydrate, sugar, fat, saturates, fibre and sodium

The energy value and the proportion of nutrients must be declared in specific units per 100 grams or per 100 milliliters. Information on vitamins and minerals must be expressed as a percentage of the recommended daily allowance (RDA).

The information on the label must be presented in tabular form with the numbers aligned or if space does not permit, in linear form in a language easily understood by the purchaser.

C. Product-Specific Labeling

For a number of products, specific labeling requirements have been established in addition to the general requirements described above. These include:

- novel foods
- foodstuffs for particular nutritional uses including dietetic and baby/infant foods
- beef
- wine
- spirit drinks
- organic foods
- cocoa and chocolate products, sugars, honey, fruit juices and similar products, preserved milk,
- coffee extracts and chicory extracts, fruit jam, jellies, marmalades, and chestnut puree
  (More details on above products can be found in Section 7).
- fresh fruits and vegetables
- meat, eggs, dairy products, spreadable fats

SECTION 3. PACKAGING AND CONTAINER REQUIREMENTS

www.useu.be/agri/packaging.html

A. Container Contents

Unlike the other requirements covered by this guide, requirements in the Directives concerning container contents of pre-packaged products set out below are not a prerequisite for marketing a foodstuff. However, if these requirements are satisfied, free movement throughout the EU is guaranteed.

The maximum tolerable error between the actual content and the quantity indicated on the label, and methods to check this are fixed in Council Directive 76/211/EEC, as amended. A small "e" of at least 3 mm on the label guarantees that the actual content corresponds to the quantity indicated. The size of the figures indicating the quantity depends on the nominal quantity:
nominal quantity greater than 1000 g or 100 cl: at least 6 mm high; greater than 200 g/20 cl but less than 1000 g/100 cl: at least 4 mm; greater than 50 g/5 cl but less than 200 g/20 cl: at least 3 mm; less than 50 g/2 cl: 2 mm. The size is followed by the unit of measurement.

Container sizes have been prescribed for butter, fresh cheeses, salt, sugar, breakfast cereals, pasta, rice, dried fruits and vegetables, coffee, frozen fruits and vegetables, fish fillets, fish fingers, ice-cream, preserved fruits and vegetables and products sold in metal containers. (Council Directive 80/232/EEC)

B. Packaging Waste Management

Member States are required to take measures to reduce packaging waste and must introduce systems for reuse, recovery and recycling of packaging materials (Council Directive 94/62/EC). To facilitate collection, reuse and recovery including recycling, an identification system for packaging has been drawn up (Commission Decision 97/129/EC). Its use is voluntary.

C. Materials in Contact with Foodstuffs

Council Directive 89/109/EEC specifies the common rules for all materials that come into contact with foodstuffs and provides for the adoption of specific directives including lists of authorized substances, conditions of use, migration limits, purity standards. To date, specific directives have been developed for vinyl chloride, certain epoxy derivatives, plastics, regenerated cellulose film, ceramics. In the case of ceramics, migration limits have been established for two of their constituents, namely lead and cadmium. Materials must bear an indication ”for food use”, which can be replaced by the specific symbol designed in Council Directive 80/590/EEC. Exporters are advised to verify if a Member State follows EU provisions as Member States are allowed to authorize provisionally the use of certain substances not listed in one of the specific directives and, for reasons of public health, they may also restrict or temporarily prohibit the use of certain materials authorized by the specific directives. The

"EU Practical Guide" explaining these directives can be downloaded from www.useu.be/agri/packaging.html.

SECTION 4. FOOD ADDITIVE REGULATIONS

www.useu.be/agri/additive.html

Council Directive 89/107/EEC provides for the establishment of EU harmonized positive lists --lists of what is permitted-- of a wide range of food additives. All food additives not included in the positive lists are prohibited except for those new food additives that receive a temporary two year authorization by Member States. Processing aids and flavorings fall outside of the scope of this directive. *Also, substances added to foodstuffs as nutrients such as minerals, trace elements, vitamins do not fall under the scope of this directive and continue to be subject to Member States legislation.*

The lists of authorized food additives and their conditions for use are published in three directives:

1) European Parliament and Council Directive 94/35/EC on **sweeteners** for use in foodstuffs. The annex to this directive lists maximum usable doses for sweeteners in selected foodstuffs.

2) European Parliament and Council Directive 94/36/EC on **colors** for use in foodstuffs.
Annex I: list of permitted food colors. Only substances listed in this annex may be used
Annex II: foodstuffs which may not contain added colors
Annex III: foodstuffs to which only certain permitted colors may be added
Annex IV: colors permitted for certain uses only
Annex V: colors permitted in general and the conditions of use therefore. Colors permitted following the "quantum satis" principle (no maximum specified) are listed in the Appendix

3) European Parliament and Council Directive 95/2/EC, as amended, the so-called **miscellaneous additives** directive on food additives other than colors and sweeteners.
Annex I: list of food additives permitted for use in foodstuffs (excl. those listed in Annex II) following the "quantum satis" principle
Annex II: list of foodstuffs in which only a limited number of additives of Annex I may be used. These include cocoa and chocolate products, fruit juices and nectars, jam and jelly, dehydrated milk and cream, fruits and vegetables, rice, oils and fats, certain cheeses, minced meat, bread and pasta, wines and beer
Annex III: list of conditionally permitted preservatives and antioxidants
Annex IV: list of other permitted additives
Annex V: list of permitted carriers and carrier solvents
Annex VI: list of additives permitted in foods for infants and young children

These lists can be downloaded from our additives webpage.

An important difference from U.S. legislation is the use of flour bleaching agents: chlorine, bromates and peroxides are not allowed in the EU.

Specific information on authorized additives can be obtained from our office. Upon request, our office can also provide a multilingual list of all food additives.

Labeling requirements for additives and flavorings are laid down in directive 2001/13/EC (general labeling directive), regulation 50/2000/EC (GM additives) and directive 89/107/EEC.
The addition of a new food additive to the EU positive list is a lengthy process. However, any Member State can allow the domestic use of a new food additive on their territory for a two year period. Companies are advised to submit an application to the Member State where they want to start using a new additive and simultaneously to the Commission. Procedures on obtaining the 2-year waiver differ from one Member State to another, and the time necessary to obtain approval also can vary significantly. The procedure for inclusion of an additive in the positive list requires that a dossier be sent to the EU Scientific Committee and to the Commission. The EU Scientific Committee reviews a substance and has to give a positive opinion before the Commission can propose the addition to the positive list. The Scientific Committee review takes a minimum of one year; the procedure to adopt a substance proposed by the Commission takes at least 18 months. Guidelines on preparing an application dossier requesting authorization of an additive can be obtained from our office.

Processing Aids

A list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their conditions of use has been established in Council Directive 88/344/EC.

Flavorings

In an initial step to harmonize the use of flavorings in the EU, the European Commission has compiled a register of all flavoring substances authorized in the different EU Member States. Substances which are subject to restrictive or prohibitive measures in certain Member States have been marked. The register can be downloaded from the Internet in pdf-format at europa.eu.int/comm/food/fs/sfp/addit_flavor/flav17_en.pdf or in xls-format at europa.eu.int/comm/food/fs/sfp/addit_flavor/flavourings/flavor_en.html.

SECTION 5. PESTICIDE AND OTHER CONTAMINANTS

www.useu.be/agri/pesticides.html

The legislation on pesticides and contaminants is partially harmonized in the EU. Enforcement of both EU and remaining Member State rules is done at the Member State level.

Pesticides

EU pesticide legislation has not been fully harmonized yet and is under review. Community maximum residue levels (MRL's) take into account the work done by Codex Alimentarius and by the OECD but exceptions exist. An overview of all compounds for which harmonized MRL's have been developed are available from our website. The complete list of MRL/commodity combinations can be downloaded from the Commission's webserver at http://europa.eu.int/comm/food/fs/ph_ps/pest/index_en.htm. Pesticide MRL's for processed or composite products are based on the MRL's for the raw agricultural ingredients.

For the registration of a new pesticide in the EU, including the establishment of an MRL, an application needs to be prepared and reviewed by the relevant authorities and committees at Member State and EU level. Pesticides currently on the EU market are under review. As a result of the review, some 320 substances used in plant protection products will be withdrawn from the EU market in 2003 and a second list of around 150 substances is expected to be withdrawn soon thereafter. For pesticides which are not or no longer authorized at Community level, an import tolerance may be requested. Application dossiers are first submitted to a rapporteur Member State. The complete procedure is described on the Commission's webserver at http://europa.eu.int/comm/food/fs/ph_ps/pest/index_en.htm.

Compounds for which there is no harmonized MRL yet remain subject to Member State legislation.

Other Contaminants

EU harmonized levels are in force for nitrates in lettuce and spinach and for aflatoxin in peanuts, nuts, dried fruits, cereals and milk (Commission Regulation 194/97, as amended). As of April 5, 2002, EU wide maximum levels also apply for lead, cadmium, mercury and for 3-monochloropropane-1,2-diol (3-MCPD) in a wide range of food products, for aflatoxin in spices and for ochratoxin A in cereals and dried vine fruits. Maximum dioxin levels have been established for products of animal origin and vegetable oils. These levels are mandatory as of July 1, 2002. The maximum levels for all of these contaminants are available in the annex to Commission Regulation 466/2001, amended by Commission Regulations 2375/2001, 221/2002, 257/2002, 472/2002 and 563/2002.

The harmonized sampling plan for aflatoxins is published in Commission Directive 98/53/EC. Sampling methods for aflatoxin in spices, to be applied from February 28, 2003 onwards, were added in Commission Directive 2002/27/EC. All EU member states should apply the harmonized sampling plan for lead, cadmium, mercury and 3-MCPD since April 5, 2002 (Commission Directive 2001/22/EC -

corrected by 2001/873/EC). The sampling plans for ochratoxin A (Commission Directive 2002/26/EC) and for dioxins (Commission Directive 2002/69/EC) should be applied by February 28, 2003.

Member States requirements continue to apply for a number of other contaminants including heavy metals, certain other mycotoxins, and radioactive elements.

Residues in Animals and Animal Product

The monitoring of residues in animals and animal products is addressed separately in Council Directive 96/23/EC. This directive includes the monitoring of the above-mentioned pesticide residues but includes also the monitoring of residues of veterinary drugs and a wide range of other contaminants and undesired substances such as residues of growth promotants. The prohibition of the use of hormones in meat production is addressed in Council Directive 96/22/EEC.

SECTION 6. OTHER REGULATIONS AND REQUIREMENTS

A. Product Inspection and Registration

Member States are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further stages of marketing. In case of non-compliance, the EU hygiene directive (Com. Reg. 93/43/EEC) allows the Commission to suspend imports from third countries or introduce special conditions for products from the third country concerned, applicable on the entire EU territory.

Criteria for laboratories conducting food controls have been harmonized but it is the Member States' responsibility to designate laboratories that are allowed to perform analyses (Council Directives 89/397/EEC and 93/99/EEC). Specific detailed inspection requirements exist for animal products. Inspections are done under supervision of a veterinarian at a limited list of ports and border inspection posts.

Fresh fruits and vegetables are subject to phytosanitary controls and are checked for compliance with EU-harmonized marketing standards. These have been established for apples and pears, apricots, artichokes, asparagus, aubergines (eggplant), avocados, beans, brussels sprouts, cabbage, carrots, cauliflowers, celery, cherries, citrus fruit, courgettes (zucchini), cucumbers, garlic, kiwis, leeks, lettuce, curly and escarole chicory, melons, onions, peaches and nectarines, peas for shelling, plums, spinach, strawberries, sweet peppers, table grapes, tomatoes, watermelons, witloof chicory, for miniature produce, walnuts and hazelnuts. Marketing standards can be downloaded from www.useu.be/agri/Fruit-Veg.html.

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat and meat products, for which a waiver may be obtained from the listing requirement described below.

Inspection fees differ from one Member State to another. Measures in case of non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods (see section 7). The person/company introducing a novel food has to submit a request to the authorities in the Member States where the product will be marketed and a copy of this request has to be sent to the Commission's Health and Consumer Protection Directorate. Importers of organic products (see section 7) are required to notify the competent regulatory authority of the Member State of their activity. The introduction of foodstuffs with particular nutritional uses (see section 7) needs to be notified to the Member State where the food is sold. Exporters of vitamin-enriched foods or nutritional supplements are especially advised to check for the existence of specific Member State registration or notification requirements.

B. Certification and Documentation Requirements

AGRIM Certificates

The EU requires import licences (AGRIM certificates) for most agricultural products for which it provides market support, including grains, milk, meat, olive oil, most fruits and vegetables, wine and sugar. In order to obtain a licence an application form must be submitted and security fee must be paid to the issuing Member State. Licences vary in validity with most expiring three months after the month of issuance.

Health Certificates

Plant Products www.useu.be/agri/plantcertif.html

Phytosanitary certificates issued by APHIS have to accompany fruit, vegetable and nut shipments to the EU.

Animal Products www.useu.be/agri/certification.html

The European Community is in the process of harmonizing legislation on imports of animal products. This is a three-stage process that starts with the recognition of a country to export a certain animal product. The U.S. is recognized by the EU for nearly all animal products.

In a second stage, lists of EU approved establishments are drawn up in recognized countries. Various U.S. agencies, including FSIS, APHIS, AMS, and FDA are involved in the listing process. Establishments are subject to EU inspections prior to listing and/or to occasional EU audits after listing. Exporters should be aware that getting a plant listed can take several months. At present, the following products must come from an EU-approved establishment:

red meat	ratites	equine semen
meat products	bovine embryos	animal casings
farmed game meat	bovine semen	fish and fishery products
wild game meat	porcine semen	milk & milk products
gelatin		

Lists can be accessed through www.useu.be/agri/estab.html.

The third level is the requirement that all shipments be accompanied by animal health and/or public health certificates signed by U.S. officials to guarantee that individual lots or shipments of products meet Community requirements.

For other products the Community has not yet completed harmonization of import requirements. In these cases import regulations are still under the control of the individual Member States. This often results in the 15 Member States maintaining different sets of lists of third countries, lists of establishments, certificate requirements, and inspection programs.

Contact information for the agencies issuing export certificates is available from our website.

Processed Foods www.useu.be/agri/foodcertif.html

All animal products imported into the EU need animal or public health certification. For processed foods containing animal product, the situation is more complicated because there is no legislation specifying the percentage of dairy, egg, red meat or poultry meat that a foodstuff must contain to necessitate certification. However, the specific EU legislation applicable to the animal product in question contains certain provisions on certification.

Red meat & poultry meat: Products containing any amount of red meat or poultry meat must be certified.

Egg products & dairy: Certification of products containing egg products or dairy products depends on the composition of the product in relation to the definitions in the relevant Community legislation.

As a rough guideline, if foodstuffs contain more than 50 percent of egg products/dairy products, the Commission believes they should be considered as such. More details are available from our website. Further, the competent authorities of the importing EU Member State should be contacted for their interpretation of the Commission's guidelines.

Although there are no harmonized EU certificates for processed foods such as canned vegetables, soup broths, etc., EU member states often require that shipments be accompanied by a certificate signed by U.S. officials. Exporters should check with their importer or with the Office of Agricultural Affairs in the importing Member State which documentation is required.

SECTION 7. OTHER SPECIFIC STANDARDS

A. Genetically Modified Foods (GMOs)

www.useu.be/agri/GMOs.html

On July 25, 2001, the European Commission published proposals for regulations on Genetically Modified Food and Feed and on Labeling and Traceability for Genetically Modified Organisms. When adopted, these new regulations will repeal three (1139/98, 49/2000, 50/2000) of the four laws currently governing the regulatory review and commercialization of genetically modified food in the EU. More information on the proposals can be found on our website.

Until the proposals are adopted, four pieces of law will continue to regulate GMO's:

Council Directive 2001/18 , the revised version of Council Directive 90/220, governing the approval for environmental release and commercialization of "living" genetically modified organisms was passed on February 15, 2001 and will enter into force on October 17, 2002. Features of the revision include time limits on approvals, explicit schedules for each stage of the approval process and also calls for new legislation on traceability and labeling.

There has been an ad hoc moratorium on new approvals since 1998, created by a blocking minority of Member States. In July, 2000 and again in October 2001, Commissioners Byrne (DG SANCO) and Wallstrom (DG Environment) proposed to resume the approval process through early implementation of Directive 2001/18 but member states stressed the need to have labeling and traceability in place before moving forward. The Commission is expected to ask the member states to restart the approval process once 2001/18 enters into force (October 17, 2002).

The Health and Consumer Protection Directorate General (DG SANCO) administers the Novel Foods Regulation **(European Parliament & Council Reg. 258 /97)** governing food safety assessments and labeling for most genetically modified foods. The Commission's new proposal on GM food & feed will replace provisions for products containing GMO's in the Novel Foods Regulation by extending the labeling requirement to products produced or derived from GMO's (with the exception of processing aids). However, in the interim, labeling of all new processed foods and food ingredients, including those made from GMO's, will remain under Novel Foods.
The regulation lacks implementing detail, so it is up to each Member State to determine thresholds, testing methods, and what products to test. Products considered "substantially equivalent" by a national food assessment body as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances, may follow a simplified procedure. They do not need full approval under Novel Foods to be placed on the market, as long as an application has been made and all Member States have been notified. This provision will change under the new proposal which annuls approval through equivalence.

Council Regulation 1139/98 in force from September 1998 covers labeling of foodstuffs derived

from Round-Up Ready soybeans and Novartis Bt-176 corn, as these products were commercialized before the Novel Foods law went into effect. This regulation has been amended by Commission Regulation 49/2000, which entered into force on April 10, 2000, setting a one percent threshold for adventitious (accidental) contamination during e.g. cultivation, harvest, transportation, storage and processing. This amendment applies to products for which the manufacturer cannot guarantee that each of the ingredients contains less than one percent GMO's. Evidence must be supplied to the competent authorities that appropriate steps were taken to avoid the presence of GMO's.

Until the new regulations on Labeling and Traceability and GM Food & Feed are in place, the precise details about which products processed from GMO's must be labeled, what testing is required or even how a product can be determined "GMO-free" will remain unclear. Exporters should work with member states authorities to register their products and to obtain insight in the member states' interpretation of EU rules.

Commission Regulation 50/2000, which also entered into force on April 10, 2000, provides specific labeling requirements for food and food ingredients containing additives and/or flavorings that have been genetically modified or have been produced from GMO's, as specified in Directive 2001/18. This regulation applies to additives and flavorings for use in foodstuffs falling within the scope of Directive 89/107/EEC and Directive 88/388/EEC.

B. Novel Foods

The legislative proposals mentioned above, provide for the establishment of a separate regime to deal with the authorization and traceability of novel foods and novel food ingredients that consist of or contain or are derived from GMO's. Pre-market approval of non-GM novel foods will continue under European Parliament and Council Regulation 258/97. Once a separate regime for GMO's is adopted, the remaining non-GM categories of novel foods will consist of foods and food ingredients:

- with a new intentionally modified primary molecular structure, or
- consisting of, or isolated from, micro-organisms, fungi or algae, or
- consisting of or isolated from plants or animals, except for foods and food ingredients obtained by traditional propagating or breeding practices with a history of safe use, or
- to which a production process not currently used has been applied, where that process changes the composition or structure of the food or food ingredient significantly

So far, six non-GM novel foods were approved to be commercialized in the EU: phospholipids from egg yolk, yellow fat spreads with added phytosterol esters, dextran produced by Leuconostoc mesenteroides, pasteurized fruit preparations pasteurized by high-pressure treatment, trehalose and coagulated potato proteins. Two products were refused: the herbal product Stevia Rebaudiana and Nangai nuts.

C. Dietetic or Special Use Foods

www.useu.be/agri/partnutr.html

Council Directive 89/398/EEC is a framework directive laying down rules for foodstuffs intended for particular nutritional uses. These are foodstuffs which, due to their special composition or manufacturing process, can clearly be distinguished from foodstuffs for normal consumption. Commission Directive 2001/15/EC lists the chemical substances in each category of nutritional substances (vitamins, minerals and amino acids) that may be added for specific nutritional purposes in foodstuffs for particular nutritional uses.

Provisions including compositional and hygiene requirements, provisions regarding the quality of raw materials, a list of additives/substances, specific labeling requirements, sampling procedures and analysis methods have been laid down in specific directives for four product categories:

- Commission Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children.
- Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction.
- Commission Directive 91/321/EC on infant formula and follow-on formula.
- Commission Directive 1999/21/EC on dietary foods for special medical purposes.

To take advantage of technological developments, the Commission may authorize the marketing of products which do not comply with the requirements of the specific directives for a two-year period.

Specific directives on foods and beverages for sports people and on foods intended for diabetics will be drafted in the future. Meanwhile, these foodstuffs remain subject to Member State legislation. The introduction of foodstuffs intended for particular nutritional uses for which no specific rules are set must be notified to the Member State where the food is sold.

D. Beef Labeling

A compulsory beef labeling scheme has been in place since September 2000. Full implementation of the beef labeling scheme went into effect on January 1, 2002. Under this scheme, labels for all bovine meat must indicate the following information:

- "Born in: name of third country"
- "Reared in: name of third country or third countries".
- For beef derived from animals born, raised and slaughtered in the same third country, the above indications may be combined as "Origin: name of third country"
- a reference number ensuring the link between the meat and the animal or animals
- "Slaughtered in: third country / approval number of slaughterhouse"
- "Cutting in: third country / approval number of cutting plant"
- A traceability code linking the meat to the animal or a group of animals representing the

production of maximum one day.

E. Wine, Beer and Other Alcoholic Beverages

The United States and the EU are in the midst of negotiating a bilateral agreement on wine. Exports of U.S. wine to the EU continue under derogations which permit certain U.S. oenological practices which would otherwise be prohibited. The current derogations for U.S. wine making practices and certification is currently set to expire in December 2003 (Council Regulation 1037/2001).

Commission Regulation 883/2001 lays down detailed rules for implementing Council Regulation 1493/1999 as regards trade with third countries in wine, grape juice and grape must. All U.S. wine imports must be accompanied by the certificate and analysis report or VI1-form (Annex VII of 883/2001) that certifies its origin and compliance with EU standards. Under the current regulation the producers may issue the certification themselves if they provide certain assurances. A list of U.S. agencies/laboratories/wine producers authorized to draw up VI1-forms was published in Official Journal C 184 of June 29, 2001, or can be obtained from the Bureau of Alcohol, Tobacco and Firearms (www.atf.treas.gov).

Commission Regulation 753/2002 lays down new wine labeling rules, scheduled to come into force on January 1, 2003. It also regulates the protection of certain traditional expressions linked to a geographical origin, e.g. "ruby" for port from Portugal. Title V of the regulation outlines provisions applying to third country wines. Third country wines may include geographical indications on the label under certain conditions.

Council Regulation 1576/89 as amended, lays down the general rules on the definition, description and presentation of spirit drinks. There is no Community legislation for beer; although some Member States have adopted national provisions to make the list of ingredients compulsory.

F. Organic Foods

www.useu.be/agri/organic.html

Council Regulation 2092/91, as amended, on organic products covers the following requirements and definitions: production and processing methods, labeling and marketing, inspection and imports from third countries. It was supplemented by Regulation 1804/99 to include livestock production. The term “organic” on the label may only be used for product conforming these regulations.

While organic standards have been set at the EU level, implementation and enforcement of the regulation is the responsibility of the individual member states. This member state responsibility also extends to imports of organic products. In order to import U.S. organic products, EU importers must work through their designated member state authority to obtain an import authorization. These authorizations are granted on a case-by-case basis, subject to the member state’s review of two main elements: the organic standards and inspection measures applied by the certifier of the product and the certifier’s compliance with EN 45011 or ISO Guide 65.

The importer must demonstrate that the product was produced according to standards equivalent to the EU standards. In addition, the importer must provide evidence that the certifier of the product has been accredited to EN 45011/ISO 65 by an authority recognized by the member state. Individual member states may have different criteria for judging compliance with these requirements. In the U.S., USDA's Agriculture Marketing Service (AMS) has been designated as the competent authority to accredit U.S. organic certifiers for compliance with ISO 65. To date, Austria, Netherlands, Denmark, Spain, Sweden, United Kingdom and certain German states have officially recognized AMS' ISO 65 accreditation.

On September 7, 2001, the EU published Commission Regulation 1788/2001 laying down detailed rules for a certificate of inspection for imports from third countries. Scheduled to come into force on July 1, 2002, but postponed until November 2002, certifiers of U.S. organic products will have to use the EU certificate format for products to be exporter to the EU. An original certificate must accompany the good and will be verified at the border by the member state authorities. The goods will not be released until the authorities have verified that a valid import authorization has been granted for the consignment. Member states have several options for implementing the regulation, which means that procedures may differ from member state to member state. Depending on the procedure adopted by a particular member state, there is potential for delays at the border while verification of the import authorization takes place. The regulation includes a requirement for member states to communicate their procedures to the Commission before April 2002. The Commission may make this information available to interested parties.

G. Vertical Legislation (Breakfast Directives)

www.useu.be/agri/vertic.html

Vertical legislation on the manufacture and marketing of specific products has been developed for:

- cocoa and chocolate products
- sugars
- honey
- fruit juices and similar products
- preserved milk
- coffee extracts and chicory extracts
- fruit jams and similar products

H. Animal Products

- Council Regulation 1907/90 establishes marketing standards for eggs
- Council Regulation 1906/90 of 26 June 1990 on certain marketing standards for poultry
- Council Regulation 1898/97 limits the use of the word "milk" or other dairy products to actual dairy products

- Council Regulation 2991/94 establishes standards for spreadable fats
- Council Regulation 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products
- Commission Regulation 1825/2000 laying down detailed rules on the labeling of beef and beef products

Product briefs on seafood and petfood can be found on our website at www.useu.be/agri/seafood2.html and www.useu.be/agri/petfood.html.

I. Frozen Foodstuffs

www.useu.be/agri/frozen.html

Council Directive 89/108/EEC sets rules for quick-frozen foodstuffs and for their packaging and labeling. Quick-frozen foodstuffs sold to the final consumer should carry the following additional labeling indications: the product name with the indication "quick-frozen", the date of minimum shelf life, the period during which the purchaser may store the product , the storage temperature and/or type of storage equipment required, batch identification and a clear indication of the type "do not re-freeze after defrosting".

J. Irradiated Foodstuffs

www.useu.be/agri/irradiation.html

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU- wide approval.

- **Framework Directive 1999/2/EC** outlines the marketing, labeling, import and control procedures and technical aspects of food irradiation. Irradiated foods must be labeled "irradiated" or "treated with ionizing radiation" even if the irradiated ingredients used in compound ingredients constitute less than 25% of the finished product.

- **Implementing Directive 1999/3/EC** establishes a Community list of foods and food ingredients authorized for irradiation treatment. The list contains only one food category: "dried aromatic herbs, spices and vegetable seasonings". Until the positive list is expanded, the national authorizations listed on our website continue to apply.

SECTION 8. COPYRIGHT AND /OR TRADEMARK LAWS

www.useu.be/agri/commu.html

Community trademark policy was created by Council Regulation 40/94 and implemented by Commission Regulation 2868/95. This regulation creates a single, unitary registration system covering the whole Community territory.

In practice, a Community trademark must meet two conditions: it must be a sign which can be represented in graphic form, and it must make it possible to distinguish goods and services from those of another company. It is valid for a period of 10 years. Applications for registering Community trademarks under these regulations may be filed with the Alicante, Spain, based Office of Harmonization for the Internal Market, subject to the fees set out in Commission Regulation 2869/95, or at a national industrial property office in a Member State of the European Union.

On completion of the registration procedure, the trademark is registered in the Register of Community trademarks.

Before the introduction of the Community trademark, two different systems were in place for registering trademarks in countries of the European Union. First, companies had the option of applying for an international trademark that applies in the countries which have signed the Treaty of Madrid. However, the U.S. did not sign this convention and only the following nine EU countries signed it: Belgium, Germany, Spain, France, Italy, Luxembourg, the Netherlands, Austria and Portugal. The second option was to apply for national trademarks in the individual countries of the EU. However, the only means for protection of a trademark for the whole Community territory was to file twelve applications for the registration of the mark at the national trademark offices of the respective Member States plus an application at the common trade mark office of the three Benelux countries, dealing with a total of thirteen different trademark registration systems in eleven different languages.

With the introduction of Community trademarks, a third system was added and Community, national and international trademarks co-exist within the Member countries of the European Union.

SECTION 9. IMPORT PROCEDURES

http://www.useu.be/agri/import.html
http://www.useu.be/agri/customs.html

Council Regulation 2913/92 establishes the Community Customs Code. The Code lists all the customs procedures applicable to the trade in goods with third countries. Import duties are determined by the tariff classification of goods and by the customs value. With the implementation of the Code, the 15 member states of the European Union form a customs union which means that all the member states apply the same tariff on goods imported from outside the EU. Once an imported good is cleared in one member state, it can move freely throughout the EU.

The EU uses the Combined Nomenclature (CN) for the customs classification of goods. The CN eight digit code numbers are based on the Harmonized System (HS) nomenclature: the first six digits refer to the HS headings, the two following digits represent the CN subheadings. The EU's on-line customs database can be consulted to look up commodity codes and relevant import duties: http://europa.eu.int/comm/taxation_customs/dds/en/tarhome.htm. It is also possible to obtain Binding Tariff Information (BTI) from a member state's customs authority to get the proper product classification. Through this system, traders know in advance the tariff classification of the goods they intend to import. BTI is legally binding in all the member states. A list of customs authorities can be found on the Internet at http://europa.eu.int/comm/taxation_customs/databases/bti/EN.pdf. The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading.

Goods are only released after payment of the import duty and other taxes that may be due. Duties payable on goods imported into the EU may include:

- import duty (expressed as ad valorem tariffs or specific tariffs per unit weight/volume/number of pieces)
- additional duties on flour and sugar (processed products)
- entry price (fruit and vegetables)
- environmental taxes - not harmonized
- inspection fees - not harmonized
- Value Added Tax (VAT) - not harmonized
- excise duties (alcohol and tobacco) - not harmonized

A list of VAT rates applicable in the different member states can be found on the Internet at http://europa.eu.int/comm/taxation_customs/publications/info_doc/taxation/tva/taux_tva-2002-5-1en.pdf.

A list of excise duties applicable on alcoholic beverages and tobacco can be found at http://europa.eu.int/comm/taxation_customs/publications/info_doc/taxation/c4_excise_tables.pdf.

Other customs procedures described in detail in the Code include entry into free zones, situations where no import duty is payable: e.g. the inward processing regime, under which goods can be imported for processing but the finished product must be exported from the Community market. The Code also provides for a two-stage right of appeal lodged in the Member State where a decision has been taken or applied for: in the first instance to the customs authority, then to the national courts.

APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS

Commission of the European Communities
Rue de la Loi 200
1049 Brussels
Belgium
Tel: (32-2) 299 11 11
For more specific information on the European Commission, please contact our office

United States Mission to the European Union
Office of Agricultural Affairs
Mailing address:
27 Boulevard du Regent
1000 Brussels
Belgium
Tel: (32-2)508-2760
Fax: (32) (2) 511-0918
e-mail: AgUSEUBrussels@fas.usda.gov

Office for Harmonization in the Internal Market
Avenida de Aguilera, 20
03080 Alicante
Spain
Tel. (34-96) 513 92 43
Fax. (34-96) 513 91 73

USDA/FDA contacts for certification of Animal Products www.useu.be/agri/certification.html

Other FAS Offices in the European Union www.useu.be/agri/other.html

APPENDIX II. HOW TO OBTAIN EU LEGISLATION

www.useu.be/agri/legis.html

European Commission's Eur-lex website

http://europa.eu.int/eur-lex/

The Official Journal http://europa.eu.int/eur-lex/en/oj/index.html

The Official Journal is the EU equivalent to the U.S. Government's "Federal Register". The L (Legislation) and C (Information and Notices) series of the Official Journal appear daily. Full texts in the 11 official languages of the European Union, including tables and graphics, are available on the "Eur-lex" website.

Sales Offices

Subscriptions and paper editions of the Official Journal can also be obtained from one of the sales offices in the U.S.:

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Legislation in force http://europa.eu.int/eur-lex/en/lif/index.html

The texts are arranged under twenty main chapter headings. Legislation relating to agriculture,

biotechnology, organic farming, foodstuffs, etc. can be found under heading 03 "Agriculture" and heading 15 "Environment, Consumers and Health Protection". An alphabetical index using keywords is also available. On this site you can find the initial legislation and all the amendments as published in the Official Journal.

Consolidated texts http://europa.eu.int/eur-lex/en/consleg/index.html

"Consolidated" means that the texts of all the amendments have been incorporated into the text of the basic act. The consolidated texts are for information purposes only and therefore not legally binding. Under "analytical structure" you will find the same 20 thematic chapters. A chronological index arranged by year of adoption is also available. Please note that not all EU legislation is available through this service.

Preparatory Acts http://europa.eu.int/eur-lex/en/com/index1.html

List of Commission Proposals that have not yet been adopted and links to documents of other European Institutions that take part in the development of Community legislation.

APPENDIX III. EU INITIATIVES

This report gives an overview of EU food laws currently in force. However, below follows a list of EU proposals / initiatives that may possibly affect U.S. food exports to the EU:

- Additives
- Allergen labeling
- Food contact materials
- Food hygiene and traceability
- Foods for sport people
- Foods for diabetics
- Fortified foods
- Fruits & Vegetables (conformity checks)
- Geographical indications
- GM approval process
- GM labeling and traceability
- Irradiation
- Nutrition, functional and health claims
- Pesticides in baby foods and formulae
- Smoke flavorings
- Sweeteners
- Zoonoses

Please check our website (www.useu.be/agri/usda.html) for updates on legislative developments.